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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/721,652

Applicant(s)

GIBSON ET AL.

Examiner

Bethany Barham

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2008 and 23 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1.5-8,10,11 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1.5-8,10,11 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Summary

Receipt is acknowledged of the Applicants' Response and Amended Claims filed on 1/22/08. Claims 1, 5-8, 10-11, and 26 are pending in this action. Claims 1, 5-8, 10-11 and 26 are rejected.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/23/08 has been entered.

Due to Applicant's amendments the previous 102 rejection of record is hereby withdrawn. All other rejections are maintained.

MAINTAINED REJECTIONS

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5-8, and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lesens et al US 6,399,124 B1.

Lesens et al teaches the limitations of claims 1 and 5:

- Lesens et al teaches composition comprising fermentable fibers specifically promoting the growth, in the intestinal tract, of the lactic acid bacteria contained initially in the ice cream for the treatment and/or prevention of gastrointestinal disorders, for strengthening the immune system, or for increasing the absorption of minerals (abstract).
- Lesens et al teaches the composition contains prebiotic fibers (abstract), which may be of a protein or saccharide nature, chosen for example from vegetable pectins, chito-, fructo-, gentio-, galacto-, isomalto-, manno- or xyloligosaccharides, etc (col. 4, lines 44-47; and claim 2). The preferred galactooligosaccharides comprise a saccharide part consisting of 2 to 5 repeating units and preferred fructooligosaccharides are inulin-oligofructoses extracted from chicory which may comprise, for example, 1-9 repeating units (col. 4, lines 56-64; and claim 26). Examples 1, 4 and 5 specifically teach edible compositions, coatings and decorations containing galactooligosaccharide P7L, Raftilose L30 and Actilight 950P.
- The composition of Lesens et al teaches that the quantity of fibers in the dessert may contain from 0.1 to 20% of such fibers (by weight relative to dry matter content), and that a single dessert may be designed to provide up to a maximum of 10 g of fiber per dessert (col. 5, lines 15-25).

- Examples 4-5 of Lesens et al teach a cone made of Raftilose L30 (Table 7) or wafer dough of galactooligosaccharide P7L, respectively; and a decoration or coating such as that of Table 3 (galactooligosaccharide P7L) or Table 4 (Raftilose L30). Such a ratio would yield a weight ratio of 1.56 FOS:GOS in the single food composition.
- Example 4 teaches 1.1 g fibers are provided per ice cream cone, while Example 6 teaches 2.1 g of fiber from the sandwich. Claim 9 of Lesens et al teaches that about 0.1 to about 10% of the frozen dessert comprises fibers.

Lesens et al teaches the limitations of claims 6-8 and 11:

- Lesens et al teaches compositions wherein the edible support alone comprises between about 1 to about 60% milk, between about 0.5 to about 5% of animal or vegetable proteins, between about 0.1 to about 10% fibers, between about 15% to about 30% sucrose and between about 2% to about 20% fat, by weight (claim 9). Examples 1 and 2 teach that a consumption of 200 mL or 100 g of ice cream per day provides proper dietary supplement. And it is the examiners position that all examples of Lesens et al are compositions that are ready-for-consumption and high in calories.

Lesens et al teach the limitations of claim 10:

- Lesens et al teaches compositions wherein the edible support alone comprises between about 1 to about 60% milk, between about 0.5 to about 5% of animal or vegetable proteins, between about 0.1 to about 10% fibers, between about 15% to about 30% sucrose and between about 2% to about 20% fat, by weight (claim

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9). But examples 4-6 also teach compositions comprising flour, which provides a significant amount of carbohydrates (52g - 62g flour/100g total weight).

- Lesens et al does not teach a composition of claim 10 or the specific ratio claimed in instant claim 1.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to Lesens et al to make a composition of FOS and GOS in a specific ratio, proteins, carbohydrates, and fats, and one of ordinary skill in the art would be motivated to experiment and optimize values to obtain workable ranges. As stated in MPEP 2144.05: "[W] here the general conditions of a claim are disclosed in prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." The skilled artisan would know how to optimize the amounts taught by Lesens et al to obtain the optimal gastrointestinal benefit, since Lesens et al teaches a composition of fibers wherein the fibers are preferably FOS and GOS and teaches various examples comprising both.

Claims 1, 5, 7-8 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moro et al and Boehm et al and Rigo et al in view of Lesens et al US 6,399,124 B1.

Moro et al and Boehm et al and Rigo et al in view of Lesens et al teach the limitations of claims 1, 5, 7-8, and 10-11:

- Moro et al. disclose infant formula comprising a combination of galactooligosaccharides (GOS) and fructooligosaccharides (FOS), fat, and protein (See pages 291, 294 and Table 1). According to Moro et al., the oligosaccharide mixture can comprise between the 90% GOS and 10% FOS (page 292). This satisfies the weight ratio of FOS:GOS of about 0.01 to about 50. According to Table 1, the oligosaccharide mixture can comprise between about 0.05 to about 40% by weight, based on the total formulation. As formulated, it is the examiner's position that the formula advanced by Moro et al. is both "nutritionally complete" and "ready-for-consumption."
- Boehm et al. disclose infant formula comprising a combination of galactooligosaccharides (GOS) and fructooligosaccharides (FOS), fat, and protein (See page F179 and Table 1). According to Boehm et al., the oligosaccharide mixture can comprise between the 90% GOS and 10% FOS (page F178). According to Table 1, the oligosaccharide mixture can comprise between about 0.05 to about 40% by weight, based on the total formulation. As formulated, it is the examiner's position that the formula advanced by Boehm et al. is both "nutritionally complete" and "ready-for-consumption."
- Moro et al and Boehm et al do not teach a composition comprising more than about 1 g of protein in 100 kcal of claim 7.
- Rigo et al. disclose infant formula comprising a combination of galactooligosaccharides (GOS) and fructooligosaccharides (FOS), fat, and protein (See Table 1). According to Table 1, the oligosaccharide mixture can

comprise between about 0.05 to about 40% by weight, based on the total formulation, and over 1% of protein can be present per 100 kcal. As formulated, it is the examiner's position that the formula advanced by Rigo et al. is both "nutritionally complete" and "ready-for- consumption."

- Moro et al, Boehm et al, and Rigo et al do not teach the exact percentages of ingredients and ratio of GOS to FOS as claimed.
- Lesens et al is taught above. Lesens teaches the ratio and percentages.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to Moro et al and Boehm et al and Rigo et al in view of Lesens to make an composition comprising a mixture of prebiotic fibers such as FOS and GOS, and other ingredients for consumption. One of ordinary skill in the art would be motivated to experiment and optimize values to obtain workable ranges to treat those with gastrointestinal disorders, to promote the growth, in the intestinal tract, of the lactic acid bacteria, also for strengthening the immune system, or for increasing the absorption of minerals. As stated in MPEP 2144.05: "[W] here the general conditions of a claim are disclosed in prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." Because the exact formulation and portion of a baby formula, nutritional supplement, or other edible composition is determined by age, size, health, and other variables it would be reasonable for one of ordinary skill in the art to experiment and optimize the values set forth in Moro et al and Boehm et al and Rigo

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et al in view of Lesens et al in order to obtain a composition capable of delivering the appropriate amount of nutrients to the patient.

Claims 1 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lesens et al US 6,399,124 B1 in view of Van Leeuwen et al US 2003/0138476 A1.

Lesens et al in view of Van Leeuwen et al teach the limitations of claims 1, and 26:

- Lesens et al is taught above and claim 1 is taught above. Lesens et al teaches composition comprising fermentable fibers specifically promoting the growth, in the intestinal tract, of the lactic acid bacteria contained initially in the ice cream for the treatment and/or prevention of gastrointestinal disorders, for strengthening the immune system, or for increasing the absorption of minerals (abstract).
- Lesens et al teaches the composition contains prebiotic fibers (abstract), which may be of a protein or saccharide nature, chosen for example from vegetable pectins, chito-, fructo-, gentio-, galacto-, isomalto-, manno- or xyloligosaccharides, etc (col. 4, lines 44-47; and claim 2). Examples 1 and 2 teach that a consumption of 200 mL or 100 g of ice cream per day provides proper dietary supplement.
- Lesens et al does not teach including glutamine, but does teach compositions containing milk, animal or vegetable proteins, which are known to contain glutamine (claim 9).
- Van Leeuwen et al teach nutritional preparations such as baby food or enteral food (abstract) which include prebiotics such as fructo-oligosaccharides and

galacto-oligosaccharides and further glutamine or an equivalent such as is known in the art (pg. 1, [0013-0014], pg. 2, [0017]). Further, Van Leeuwen et al claims a nutritional preparation as a nutritional preparation with also contains glutamine or equivalent thereof and further prebiotics such as galacto-oligosaccharides and fructo-oligosaccharides (claims 1-3, 8, and 12).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the compositions as taught by Lesens et al with glutamine as taught by Van Leeuwen et al. One of ordinary skill in the art would have been motivated to combine the teachings since both teach nutritional compositions that help the intestinal tract and provide fibers such as prebiotics (galacto-oligosaccharides and fructo-oligosaccharides). As such one would have a reasonable expectation of success in adding the glutamine of Van Leeuwen et al to the compositions of Lesens et al, especially since Van Leeuwen et al teaches that products which are rich in glutamine include vegetable proteins (pg. 1, [0005]), as is already taught by Lesens et al (claim 9).

Response to Arguments

Applicant's arguments with respect to claims 1, 5-8, 10-11 and 26 have been considered but not persuasive and are moot in view of the new grounds of rejection necessitated by applicants' amendments. Applicants argue that Lesens et al does not teach compositions comprising a blend of galacto-oligosaccharides and fructo-oligosaccharides. The Examiner respectfully disagrees, as Lesens et al teach both galacto-oligosaccharides and fructooligosaccharides are preferred and claims "mixtures

thereof" (col. 4, lines 56-64; and claim 26). Furthermore, Lesens et al teaches in examples 1, 4 and 5 ice cream put into a cone or wafers containing either (galacto-oligosaccharides or fructo-oligosaccharides) that is coated with composition of Table 2 (containing galacto-oligosaccharides) or Table 3 (containing galacto-oligosaccharides) and decorated with a topping of Table 4 containing fructooligosaccharides. Lesens et al further claims fibers of between about 0.1 to about 10% including fibers like galacto-oligosaccharides and fructo-oligosaccharides (claims 1-2, and 9) and as such that these fibers are useful for promoting the growth of the lactic acid bacteria in a human intestinal tract. Lesens et al renders obvious the instant claims 1,3,5-8 and 10-11.

Applicant also argues that the prior art does not teach synergistic effect of FOS and GOS, however Lesens et al does teach that the edible composition containing the fibers (FOS and GOS) promote the growth of the lactic acid bacteria in a human intestinal tract (abstract, claim 1) and as such proves that these fibers enhance lactic acid bacteria growth. The property or function of promoting lactic acid bacteria by ingestion of FOS and GOS are not separable from the structure of FOS and GOS as taught by Lesens et al. Simply because Lesens is silent to the synergism of FOS and GOS does not take away from the fact that the art teaches FOS, GOS are preferred and mixtures thereof, since the prior art teaches a composition and process for forming said composition described by applicants instant application, but applicants observation that it also has 'synergistic effect' does not give it patentable weight, since it is the same composition and same process of making, as adding a characterization to a prior art patented invention is not patentable. Applicant further points to Lesens et al (col. 5,

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lines 23-36) as a teaching away, the Examiner respectfully disagrees. This section teaches that (as does claim 9) that a substantial amount of fiber (which is preferably FOS and GOS) is added to the composition, but that not more than 10 g. is added per dessert (or a total 0.1-20% by weight of fiber). The amount of fiber claimed in Lesens et al (claim 9) is not outside the scope of the instant claim 10 which claims only 2.5% fiber; therefore there is no teaching away only an 'upper limit' placed on the fiber amount.

Also, Boehm et al teaches that the combination of FOS and GOS promotes beneficial intestinal bacteria in a synergistic way so that lactobacilli can grow (pg. F178, last paragraph and Abstract "conclusion"). Moro et al teaches that the optimal dosage of the FOS and GOS mixture are 0.8 g/dL which produces a more pronounced bifidogenic effect than 0.4 g/dL, which indicates a synergistic effect of FOS and GOS (pg. 294, last paragraph-pg. 295 end); while Moro et al teaches that there was no difference in the dosages (0.4 or 0.8 g/dL) for the Lactobacilli, but that the number of Lactobacilli was significantly higher (at day 2 of the 28 day study) for both supplemental groups than the placebo group (pg. 293, last paragraph-pg. 294, lines 1-2). Rigo et al teaches that the use of prebiotics ("material and methods" uses a mix of FOS and GOS) resulted in a rapid and significant increase in the percentage of endogenous bifidobacteria and the ability to maintain a stable intestinal flora (pg. 39, summary "conclusion"). As such it is the examiners opinion that the art supports the synergistic effect of FOS and GOS in the growth of intestinal bacteria such as Lactobacilli.

Applicant's argue that there is no prima facie case of obviousness and no motivation to combine Lesens et al and Van Leeuwen et al, and the examiner

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respectfully points out that applicant's argue against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

It should be noted that the motivation to combine references can be different from the ones set forth by Applicant. That is, as long as motivation exists to combine the elements, the problem to be solved does not have to involve the same reason. As such, the examiner respectfully submits that there is motivation to combine the teachings of Lesens et al and Van Leeuwen et al and the expected result of a fiber containing composition of prebiotics (FOS and GOS) and glutamine that produces beneficial gastrointestinal results. Lesens et al teaches GOS and FOS are preferred and mixtures thereof for intestinal tract health and further Example 7 of Van Leeuwen teaches a composition of FOS and lactose while Example 3 of Van Leeuwen teaches that GOS is substituted for lactose and, as such the art seems to point to the fact that GOS can be substituted for lactose. Lesens et al teaches generically proteins and fibers (mixtures of GOS and FOS) for intestinal health, while Van Leeuwen also specifically adding glutamine and prebiotics (such as GOS and FOS) benefits the intestinal wall. Thus motivation to combine the prior art exists as both are directed to improving intestinal health with prebiotics (FOS and GOS) and proteins (Van Leeuwen teaches glutamine).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)272-6175. The examiner can normally be reached on M-F from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bethany Barham
Examiner 1615

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